UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 4, 2024

Akero Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-38944**	**81-5266573**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

601 Gateway Boulevard, Suite 350 **South San Francisco, CA** **(Address of principal executive offices)**	**94080** **(Zip Code)**

Registrant's telephone number, including area code (650) 487-6488

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	AKRO	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On March 4, 2024, Akero Therapeutics, Inc. (the "Company") issued a press release titled "Akero Therapeutics Reports Statistically Significant Histological Improvements at Week 96 in Phase 2b HARMONY Study." A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The Company from time to time presents and/or distributes to the investment community slide presentations to provide updates and summaries of its business. A copy of its HARMONY Study slide presentation is being furnished herewith as Exhibit 99.2 to this Current Report on Form 8-K.

The information under this Item 7.01, including Exhibit 99.1 and Exhibit 99.2 hereto, is being furnished herewith and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall such information be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On March 4, 2024, the Company released preliminary topline week 96 results from HARMONY, a Phase 2b study evaluating the efficacy and safety of its lead product candidate efruxifermin ("EFX") in patients with pre-cirrhotic metabolic dysfunction-associated steatohepatitis ("MASH"), fibrosis stage 2 or 3 ("F2-F3").

The study previously met its primary endpoint of ≥1 stage improvement in fibrosis with no worsening of MASH after 24 weeks of treatment for both the 50mg EFX (41%) and 28mg EFX (39%) dose groups, compared to 20% for the placebo arm. At week 96, the response rates on this endpoint increased to 75% ($p<0.001$) for 50mg EFX and 46% ($p=0.07$) for 28mg EFX, compared to 24% for placebo.

The study also met additional histology endpoints at week 96—notably 36% ($p<0.01$) and 31% ($p<0.01$) of patients treated with 50mg EFX and 28mg EFX experienced a 2-stage improvement in fibrosis without worsening of MASH—which is more than 10-fold the placebo rate of 3%. Results for all of the histological endpoints are summarized in the table below, based on either the primary analysis (patients with baseline and week 96 biopsies) or intent-to-treat (ITT) analysis (all randomized and dosed patients, with missing data imputed as non-response).

The placebo-adjusted effect size on fibrosis improvement without worsening of MASH (EFX response rate minus placebo response rate) more than doubled between week 24 and week 96 for the 50mg EFX group, with a slight increase observed for the 28mg EFX group. Specifically, the placebo-adjusted effect sizes for fibrosis improvement without worsening of MASH grew from 21% to 52% between week 24 and week 96 for 50mg EFX and from 20% to 22% for 28mg EFX. Highly statistically significant results for 50mg EFX at week 96 are notable because (1) the study was not fully powered at week 96 and (2) the placebo rate increased rather than decreased. An increase in treatment rate for placebo means that the increases in effect size are attributable to higher EFX treatment responses rather than a decline in placebo rate.

Analysis of the evolution of responses between weeks 24 and 96 indicated not only broader fibrosis improvement without worsening of MASH but also sustained response, particularly at 50mg EFX. Among those patients with available week 96 biopsies whose fibrosis improved at week 24, 92% and 83% of the 50mg and 28mg EFX groups remained responders, respectively, compared to 40% for placebo.

Analysis of a subset of patients with baseline F3 fibrosis who had week 96 biopsies showed EFX's potential to treat patients with more advanced fibrosis, who are generally considered to be at higher risk of progression to cirrhosis. For this advanced F3 patient population, 68% ($p<0.001$) and 40% ($p=0.053$) of the 50mg EFX and 28mg EFX groups, respectively, experienced at least a one-stage improvement in fibrosis without worsening of MASH, compared to 14% for placebo.

EFX was reported to be generally well-tolerated. There were no deaths. Fifteen serious adverse events were reported, which were generally balanced across dose groups. Across both EFX groups, the most frequent adverse events ("AEs") were grade 1 or 2 gastrointestinal events (diarrhea, nausea, and increased appetite), which were transient in nature. A total of three patients treated with EFX were discontinued due to AEs between week 24 and week 96 (two in the 28mg group and one in the 50mg group), compared with none for placebo.

In October of 2023, the Company reported week 36 results for the SYMMETRY study, a Phase 2b trial in patients with compensated cirrhosis (F4) due to MASH, Child-Pugh class A. The SYMMETRY study was designed to include a second biopsy after 96 weeks of treatment, for which the results remain on track to be reported in the first quarter of 2025.

Forward-Looking Statements

This Current Report on Form 8-K and certain materials furnished or filed herewith contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements regarding: the Company's business plans and objectives, including future plans or expectations for EFX, including the anticipated or potential therapeutic effects of EFX, as well as the dosing, safety and tolerability of EFX; upcoming milestones, and expected timing to report the long-term follow-up results of Akero's Phase 2b SYMMETRY study.

Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: the success, cost, and timing of the Company's product candidate development activities and planned clinical trials; the Company's ability to execute on its strategy; positive results from any of its clinical studies may not necessarily be predictive of the results of future or ongoing clinical studies; regulatory developments in the United States and foreign countries; the Company's ability to fund operations. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in the Company's annual report on Form 10-K filed, with the United States Securities and Exchange Commission (SEC) and quarterly reports on Form 10-Q filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in the Company's other filings with the SEC. All forward-looking statements contained in this presentation speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release issued by Akero Therapeutics, Inc. on March 4, 2024
99.2	Slide presentation of Akero Therapeutics, Inc.
104	Cover Page Interactive Data File (embedded within Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 4, 2024

AKERO THERAPEUTICS, INC.

By: /s/ Andrew Cheng
Andrew Cheng, M.D., Ph.D.
President and Chief Executive Officer

Akero Therapeutics Reports Statistically Significant Histological Improvements at Week 96 in Phase 2b HARMONY Study

50mg (75%, p<0.001) and 28mg (46%, p=0.07) EFX groups demonstrated ≥1 stage improvement in fibrosis without worsening of MASH, approximately three- and two-fold the placebo rate (24%)

50mg (36%, p<0.01) and 28mg (31%, p<0.01) EFX groups demonstrated ≥2 stage improvement in fibrosis without worsening of MASH, more than 10-fold the placebo rate (3%)

EFX-treated patients experienced statistically significant improvements on nearly all histological endpoints by ITT analysis as well as the primary analysis of patients with week 96 biopsies

Investor webcast at 8:00 am ET Monday, March 4, 2024

SOUTH SAN FRANCISCO, Calif., Mar. 4, 2024 — Akero Therapeutics, Inc. (Nasdaq: AKRO), a clinical-stage company developing transformational treatments for patients with serious metabolic disease marked by high unmet medical need, today released preliminary topline week 96 results from HARMONY, a Phase 2b study evaluating the efficacy and safety of its lead product candidate efruxifermin (EFX) in patients with pre-cirrhotic metabolic dysfunction-associated steatohepatitis (MASH), fibrosis stage 2 or 3 (F2-F3). The study previously met its primary endpoint of ≥1 stage improvement in fibrosis with no worsening of MASH after 24 weeks of treatment for both the 50mg EFX (41%) and 28mg EFX (39%) dose groups, compared to 20% for the placebo arm. At week 96, the response rates on this endpoint increased to 75% (p<0.001) for 50mg EFX and 46% (p=0.07) for 28mg EFX, compared to 24% for placebo.

The study also met additional histology endpoints at week 96—notably 36% (p<0.01) and 31% (p<0.01) of patients treated with 50mg EFX and 28mg EFX experienced a 2-stage improvement in fibrosis without worsening of MASH—which is more than 10-fold the placebo rate of 3%. Results for all of the histological endpoints are summarized in the table below, based on either the primary analysis (patients with baseline and week 96 biopsies) or intent-to-treat (ITT) analysis (all randomized and dosed patients, with missing data imputed as non-response).

Summary of Week 96 Biopsy Endpoints

	Primary Analysis[1]			ITT Analysis[2]		
Histology Endpoint[3] (Proportion of Patients)	**Placebo (N=34)**	**28mg (N=26)**	**50mg (N=28)**	**Placebo (N=43)**	**28mg (N=40)**	**50mg (N=43)**
≥1 stage fibrosis improvement without worsening MASH (%)	24	46	75***	19	30	49**
≥2 stage fibrosis improvement without worsening MASH (%)	3	31**	36***	2	20**	23**
Resolution of MASH without worsening of fibrosis (%)	24	62**	57**	19	40*	37*
MASH resolution AND ≥1 stage fibrosis improvement (%)	9	42**	54***	7	28**	35**

1 All patients with baseline and week 96 biopsies
2 All randomized and dosed patients, with missing data imputed as non-response
3 Biopsy scored independently by two pathologists; third available to adjudicate (which was not required)
* p<0.05, ** p<0.01, *** p<0.001, versus placebo (Cochran-Mantel-Haenszel test [CMH])

“Notwithstanding inherent limitations in making cross-trial comparisons, the statistically significant results for ≥1-and 2-stage fibrosis improvement and no worsening of MASH observed for 50mg EFX at week 96 are the largest response rates reported publicly to date for these endpoints in any MASH population,” said Stephen Harrison, M.D., medical director of Pinnacle Clinical Research and the HARMONY study’s principal investigator. “I believe the magnitude and general consistency of results observed across the Phase 2a BALANCED and Phase 2b HARMONY studies in patients with pre-cirrhotic MASH are reasons to be optimistic about results of the ongoing Phase 3 SYNCHRONY Histology study and the potential for EFX to be an important MASH medicine, if approved.”

The placebo-adjusted effect size on fibrosis improvement without worsening of MASH (EFX response rate minus placebo response rate) more than doubled between week 24 and week 96 for the 50mg EFX group, with a slight increase observed for the 28mg EFX group. Specifically, the placebo-adjusted effect sizes for fibrosis improvement without worsening of MASH grew from 21% to 52% between week 24 and week 96 for 50mg EFX and from 20% to 22% for 28mg EFX. Highly statistically significant results for 50mg EFX at week 96 are notable because (1) the study was not fully powered at week 96 and (2) the placebo rate increased rather than decreased. An increase in treatment rate for placebo means that the increases in effect size are attributable to higher EFX treatment responses rather than a decline in placebo rate.

Analysis of the evolution of responses between weeks 24 and 96 indicated not only broader fibrosis improvement without worsening of MASH but also sustained response, particularly at 50mg EFX. Among those patients with available week 96 biopsies whose fibrosis improved at week 24, 92% and 83% of the 50mg and 28mg EFX groups remained responders, respectively, compared to 40% for placebo.

Analysis of a subset of patients with baseline F3 fibrosis who had week 96 biopsies showed EFX’s potential to treat patients with more advanced fibrosis, who are generally considered to be at higher risk of progression to cirrhosis. For this advanced F3 patient population, 68% ($p<0.001$) and 40% ($p=0.053$) of the 50mg EFX and 28mg EFX groups, respectively, experienced at least a one-stage improvement in fibrosis without worsening of MASH, compared to 14% for placebo.

“We believe the statistically significant 2-stage improvement in fibrosis without worsening of MASH observed in approximately one in three EFX-treated patients sets EFX apart,” said Andrew Cheng, M.D., Ph.D., president and chief executive officer of Akero. “Today’s results show that longer exposure to EFX has the potential to yield sustained fibrosis improvement as well as widening anti-fibrotic treatment responses across the treated patient populations. We look forward to continuing our evaluation of EFX in patients with pre-cirrhotic MASH and cirrhosis due to MASH in our ongoing Phase 3 SYNCHRONY program, in which two out of three studies are actively enrolling.”

Summary of Changes in Effect Size from Week 24 to Week 96 for ≥1 Stage Fibrosis Improvement Without Worsening of MASH (%)[1]

	Placebo		28mg EFX		50mg EFX	
Measure (Mean)	Week 24 (N=41)	Week 96 (N=34)	Week 24 (N=38)	Week 96 (N=26)	Week 24 (N=34)	Week 96 (N=28)
≥1 stage fibrosis improvement without worsening of MASH, n (%)	8 (20)	8 (24)	15 (39)*	12 (46)	14 (41)*	21 (75)***
Placebo-adjusted effect size (%)	NA	NA	20	22	21	52

[1] All patients with baseline and week 96 biopsies

* $p<0.05$, *** $p<0.001$, versus placebo (CMH)

Summary of Breadth and Durability of Treatment Response for ≥1 Stage Fibrosis Improvement Without Worsening of MASH

Sustained[1] vs. New[2] Response Among Week 96 Responders	Placebo (N=34)	28mg (N=26)	50mg (N=28)
All week 96 responders, n (%)	8 (24%)	12 (46%)	21 (75%***)
Sustained response at week 96, n (%)[3]	2 (6%)	10 (38%)	11 (39%)
New response at week 96, n (%)[3]	6 (18%)	2 (8%)	10 (36%)
Proportion of week 24 responders with sustained response, n (%)[3]	2 of 5 (40%)	10 of 12 (83%)	11 of 12 (92%)
Proportion of week 24 non-responders with new response, n (%)[3]	6 of 29 (21%)	2 of 14 (14%)	10 of 16 (63%)

*** p<0.001, versus placebo (CMH)
1 Sustained response refers to patients who were responders at week 24 and remained responders at week 96.
2 New response refers to patients who were non-responders at week 24 but became first-time responders at week 96.
3 Not analyzed for statistical significance.

Fibrosis Improvement Among Patients with Advanced Fibrosis (F3)

Patients with F3 Baseline Fibrosis and Week 96 Biopsies	Placebo (N=22)	28mg (N=15)	50mg (N=19)
≥1 stage fibrosis improvement without worsening MASH (%)	3 (14%)	6 (40%)	13 (68%***)

*** p<0.001, versus placebo (CMH)

Summary of Week 96 Changes in Key Noninvasive Measures of Liver Fibrosis and Injury

Measure (LS Mean Change From Baseline to Week 96)	Placebo (n=33-35)	28mg (n=27)	50mg (n=25-28)
Pro-C3 (µg/L) (GEN2 ELISA)	-17†	-40†††	-51**
ELF Score	-0.1	-0.7**	-0.8**
Liver Stiffness (kPa) (FibroScan)	-0.6	-4.0*	-7.2***
ALT (%)	-10	-44***	-37**
AST (%)	-4	-30*	-38**

* p<0.05, ** p<0.01, *** p<0.001, versus placebo (MMRM)
††† p<0.001, versus baseline (MMRM)

Summary of Week 96 Changes in Key Cardio-Metabolic Biomarkers

Measure (LS Mean Change From Baseline to Week 96)	Placebo (n=34-35)	28mg (n=25-28)	50mg (n=26-27)
Triglycerides (%)	+8	-15***	-20***
HDL Cholesterol (%)	+5	+18*	+27***
Non-HDL Cholesterol (%)	+3	-2	-2
LDL Cholesterol (%)	+4	+3	+5
C-peptide (%)	+8	-2	-20**
HOMA-IR (%)	+7	-11	-33**
Adiponectin (%)	+17	+28†	+63**
Body Weight (kg)	-1.5	-0.3	-3.5†

* p<0.05, ** p<0.01, *** p<0.001, versus placebo (MMRM)
† p<0.05, versus baseline (MMRM)

EFX was reported to be generally well-tolerated. There were no deaths. Fifteen serious adverse events were reported, which were generally balanced across dose groups. Across both EFX groups, the most frequent adverse events (AEs) were grade 1 or 2 gastrointestinal events (diarrhea, nausea, and increased appetite), which were transient in nature. A total of three patients treated with EFX were discontinued due to AEs between week 24 and week 96 (two in the 28mg group and one in the 50mg group), compared with none for placebo.

In October of 2023, Akero reported week 36 results for the SYMMETRY study, a Phase 2b trial in patients with compensated cirrhosis (F4) due to MASH, Child-Pugh class A. The SYMMETRY study was designed to include a second biopsy after 96 weeks of treatment, for which the results remain on track to be reported in the first quarter of 2025.

Conference Call / Webcast Details

Akero will host a conference call and webcast with slide presentation at 8:00 a.m. ET today. The live webcast will be available on the Events & Presentations page of Akero's website, with the recording and presentation available immediately following the event.

About MASH

MASH (metabolic-associated steatohepatitis) is a serious form of MASLD (metabolic-associated steatotic liver disease) that is estimated to affect more than 17 million Americans. MASH is characterized by an excessive accumulation of fat in the liver that causes stress and injury to liver cells, leading to inflammation and fibrosis, which can progress to cirrhosis, liver failure, cancer and eventually death. There are no approved treatments for the condition and MASH is the fastest growing cause of liver transplants and liver cancer in the United States and Europe.

About the HARMONY Study

The Phase 2b HARMONY study is a multicenter, randomized, double-blind, placebo-controlled, dose-ranging trial in biopsy-confirmed adult MASH patients with fibrosis stage 2 or 3. The study enrolled a total of 128 patients, randomized to receive once-weekly subcutaneous dosing of 28mg or 50mg EFX, or placebo for 24-weeks, 126 of whom received at least one study dose. The primary efficacy endpoint for the study was the proportion of subjects who achieve at least one-stage fibrosis improvement without worsening of MASH at week 24. Week 96 secondary measures included ≥1 stage fibrosis improvement and no worsening of MASH, 2-stage fibrosis improvement without worsening of MASH, at least one-stage fibrosis improvement and MASH resolution, change from baseline in liver enzymes, noninvasive markers of liver fibrosis, glycemic control, lipoproteins, and body weight as well as safety and tolerability measures.

About EFX

Efruxifermin (EFX), is Akero's lead product candidate for MASH, currently being evaluated in the ongoing Phase 2b SYMMETRY, Phase 3 SYNCHRONY Histology, and Phase 3 SYNCHRONY Real-World studies. EFX has been observed to reduce liver fat and inflammation, reverse fibrosis, increase insulin sensitivity and improve lipoproteins in multiple clinical trials. This holistic profile offers the potential to address the complex, multi-system disease state of MASH, including improvements in lipoprotein risk factors linked to cardiovascular disease – the leading cause of death in MASH patients. Engineered to mimic the biological activity profile of native FGF21, EFX is designed to offer convenient once-weekly dosing and has been generally well-tolerated in clinical trials to date.

About Akero Therapeutics

Akero Therapeutics is a clinical-stage company developing transformational treatments for patients with serious metabolic diseases marked by high unmet medical need, including metabolic dysfunction-associated steatohepatitis (MASH), a disease without any approved therapies. Akero's lead product candidate, EFX, is currently being evaluated in two ongoing Phase 3 clinical trials: the SYNCHRONY Histology study in patients with pre-cirrhotic MASH (F2-F3 fibrosis) and the SYNCHRONY Real-World study in patients with MASH or MASLD. A third clinical trial, the SYNCHRONY Outcomes study in patients with cirrhosis due to MASH, is expected to be initiated in the first half of 2024. The Phase 3 SYNCHRONY program builds on the results of two Phase 2b clinical trials, the HARMONY study in patients with pre-cirrhotic MASH and the SYMMETRY study in patients with cirrhosis due to MASH. Akero is headquartered in South San Francisco. Visit us at akerotx.com and follow us on LinkedIn and Twitter for more information.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements, including, but not limited to, statements regarding Akero's business plans and objectives, including future plans or expectations for EFX, the therapeutic effects of EFX, as well as the dosing, safety and tolerability of EFX; the timing and enrollment of Akero's Phase 3 SYNCHRONY program and upcoming milestones, including the results, and expected timing to report the long-term follow-up results of Akero's Phase 2b SYMMETRY study. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include:; the success, cost, and timing of Akero's product candidate development activities and planned clinical trials; Akero's ability to execute on its strategy; positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; regulatory developments in the United States and foreign countries; Akero's ability to fund operations; as well as those risks and uncertainties set forth more fully under the caption "Risk Factors" in Akero's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, as filed with the Securities and Exchange Commission (SEC) as well as discussions of potential risks, uncertainties and other important factors in Akero's other filings and reports with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. Akero undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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Restoring Balance. Renewing Life.

Phase 2b HARMONY Data Presentation:
Topline Results from 96 Weeks of Efruxifermin (EFX) Treatment in Patients with Pre-Cirrhotic MASH

March 4, 2024

Forward Looking Statements

This presentation and the accompanying oral commentary may contain "forward-looking statements" of Akero Therapeutics, Inc. ("we," "us," "our," "Akero" or the "Company") within the meaning of the Private Securities Litigation Reform Act of 1995 relating to our business, operations, and financial conditions, including but not limited to current beliefs, expectations and assumptions regarding: the future of our business; future plans and strategies, including our expectations around the therapeutic potential and clinical benefits of Efruxifermin ("EFX"), as well as the dosing, safety and tolerability of EFX; our development plans for EFX, including our belief in the potential of EFX as a foundational MASH therapy; our preclinical and clinical results, including our safety/tolerability, laboratory measures and biopsy data from our Phase 2b HARMONY study and other related milestones; and the possibility that positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies; risks related to the competitive landscape. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "plan," "would," "should" and "could," and similar expressions or words, identify forward-looking statements. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent annual report on Form 10-K and quarterly report on Form 10-Q, as filed with the Securities and Exchange Commission, as well as discussions of potential risks, uncertainties, and other important factors in our other subsequent filings with the Securities and Exchange Commission. All information in this presentation is as of the date hereof, and we undertake no duty to update this information unless required by law.

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and the Company's own internal estimates and research. While the Company believes these third-party sources to be reliable as of the date of this presentation, it has not independently verified, and makes no representation as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, all of the market data included in this presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while we believe our own internal research is reliable, such research has not been verified by any independent source.

» EFRUXIFERMIN (EFX): A Bivalent Fc-FGF21 Fusion Protein

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HARMONY

STATISTICALLY SIGNIFICANT EFFECTS AFTER 96 WEEKS

HARMONY Trial Design: Pre-Cirrhotic (F2-F3) MASH with Liver Histology at 24 and 96 weeks

Week 24 Primary Endpoint

- ≥ 1 stage fibrosis improvement & no worsening of MASH

Week 96 Primary Analyses

- ≥ 1 or 2 stages fibrosis improvement & no worsening of MASH
- MASH Resolution & No Worsening of Fibrosis
- Fibrosis Improvement & MASH Resolution
- *Fully powered for week 24 primary endpoint; **not** fully powered for week 96 endpoints*

» Analysis Sets

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Analysis Set	N	Description
Full Analysis Set	128	All randomized subjects
Safety Set / Modified Full Analysis Set (ITT) Placebo (N=43) 28mg (N=40) 50mg (N=43)	126	All randomized and dosed subjects[1]
Week 24 Liver Biopsy Analysis Set Placebo (N=41) 28mg (N=38) 50mg (N=34)	113	All subjects with baseline and Week 24 biopsy results
Week 96 Liver Biopsy Analysis Set Placebo (N=34) 28mg (N=26) 50mg (N=28)	88	All subjects with completed second on-study biopsy

[1] The Modified Full Analysis Set includes subjects that were randomized and received at least one dose of study drug per the Statistical Analysis Plan.

» Baseline Demographics

Parameter (Units)	Placebo (N=43)	EFX 28mg (N=42)	EFX 50mg (N=43)
Age (Years)	55	57	52
Sex (% Female)	63	69	53
Weight (kg)	108	104	103
Type 2 Diabetes (%)	65	76	70
Fibrosis Stage (% F3)[1]	70	64	63
Proportion of Patients Treated with GLP-1 at Baseline (%)	21	18	9
Enhanced Liver Fibrosis (ELF) Score	9.8	9.7	9.8
Pro-C3[2] (µg/L) (GEN 2 ELISA)	125	113	145
Liver Stiffness by VCTE[3] (FibroScan) (kPa)	15	14	16
Hepatic Fat Fraction by MRI-PDFF[4] (%)	17.1	18.5	17.5
MASLD Activity Score (MAS)	5.4	5.1	5.6
Alanine Aminotransferase (ALT) (U/L)	62	50	63
Aspartate Aminotransferase (AST) (U/L)	57	42	52

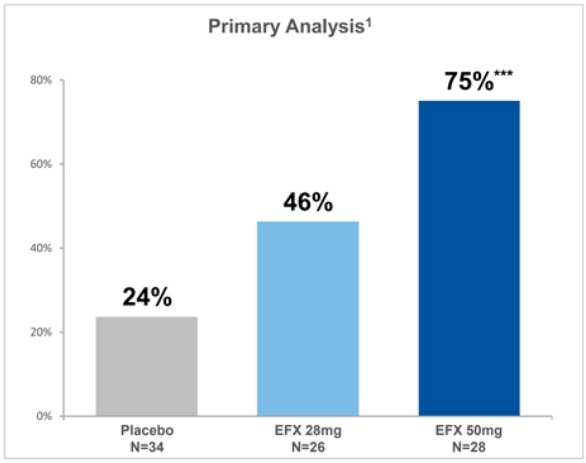
[1] All patients either fibrosis stage 2 (F2) or stage 3 (F3); [2] Procollagen 3 N-Terminal Propeptide; [3] Vibration-controlled transient elastography; [4] Magnetic Resonance Imaging Proton Density Fat Fraction

Source Data: Full Analysis Set (FAS)

≥1 Stage Fibrosis Improvement & No Worsening of MASH:
Statistically Significant Response Observed for 50mg EFX at Week 96

akero

Fibrosis Improvement ≥1 Stage & No Worsening of MASH at Week 96



[1] All subjects with baseline and Week 96 biopsies

*** p<0.001, versus placebo (Cochran-Mantel-Haenszel Test [CMH])

ITT Analysis[2]

Placebo (N=43)	EFX 28mg (N=40)	EFX 50mg (N=43)
19%	30%	49%**

[2] All missing biopsies are imputed as a non-responder

** p<0.01, versus placebo (CMH)

Source Data: Week 96 Liver Biopsy Analysis Set (LBAS-96); Modified Full Analysis Set (ITT)

≥1 Stage Fibrosis Improvement & No Worsening of MASH:
Sustained, Broad and Durable Response

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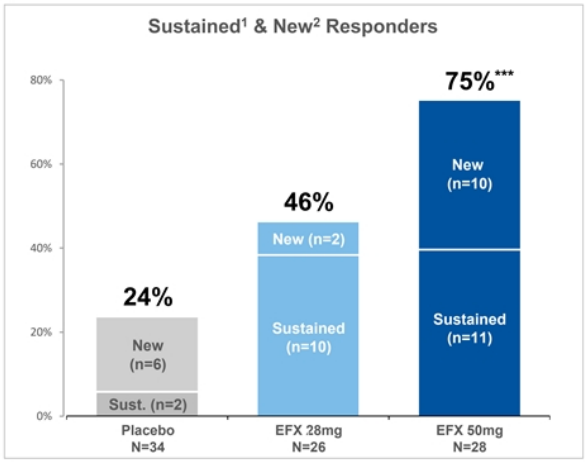
Fibrosis Improvement ≥1 Stage & No Worsening of MASH at Week 96



[1] Responder at Weeks 24 & 96; [2] Responder at Week 96 *** p<0.001, versus placebo (CMH)

Proportion of Week 24 Responders with Sustained Response at Week 96[3,5]

Placebo (N=5)	EFX 28mg (N=12)	EFX 50mg (N=12)
2 (40%)	10 (83%)	11 (92%)

Proportion of Week 24 Non-Responders with New Response at Week 96[4,5]

Placebo (N=29)	EFX 28mg (N=14)	EFX 50mg (N=16)
6 (21%)	2 (14%)	10 (63%)

[3] Among Week 24 responders with Week 96 biopsies
[4] Among Week 24 non-responders with Week 96 biopsies
[5] Not analyzed for statistical significance

Source Data: LBAS-96

EFX Fibrosis Improvement in Context: Pre-Cirrhotic MASH:
≥1 Stage Improvement in Fibrosis & No Worsening of MASH

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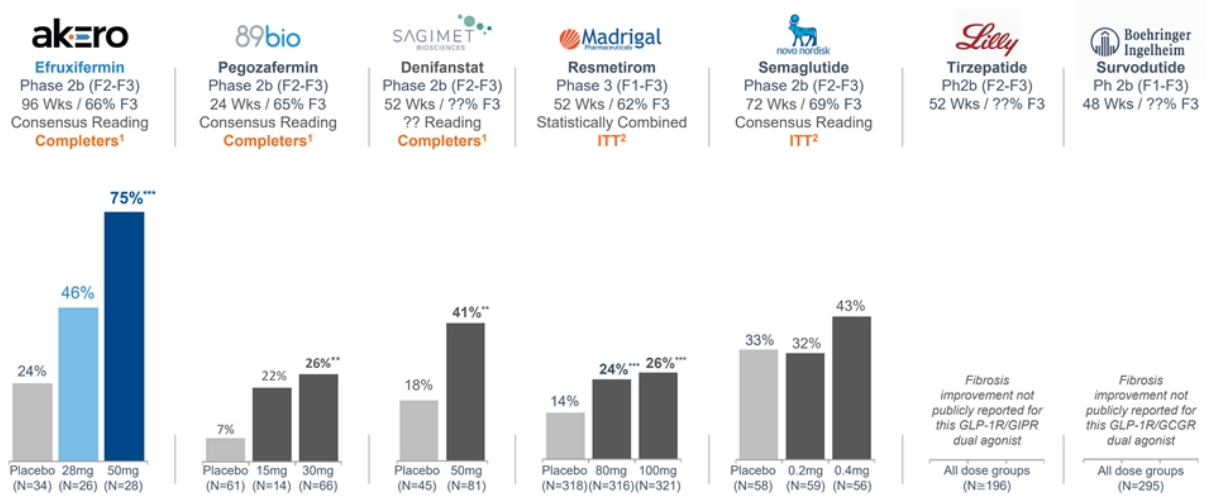

Note: These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted.

* p<0.05, ** p<0.01, *** p<0.001, versus placebo (CMH)

[1] Baseline and end-of-study biopsies available; [2] Missing biopsies imputed as non-responders

Pegozafermin - 89Bio (2023) March 22 Corporate Presentation; Denifanstat – Sagimet (2024) January 22 Press Release; Resmetirom – Madrigal (2022) December 19 Press Release; Semaglutide - Newsome et al. (2021) New Engl J Med 384, 1113-24; Tirzepatide – clinicaltrials.gov, NCT04166773; syrvodutide – clinicaltrials.gov, NCT04771273; All trademarks are the property of their respective owners.

2 Stage Fibrosis Improvement & No Worsening of MASH:
Statistically Significant Response Observed for Both EFX Groups

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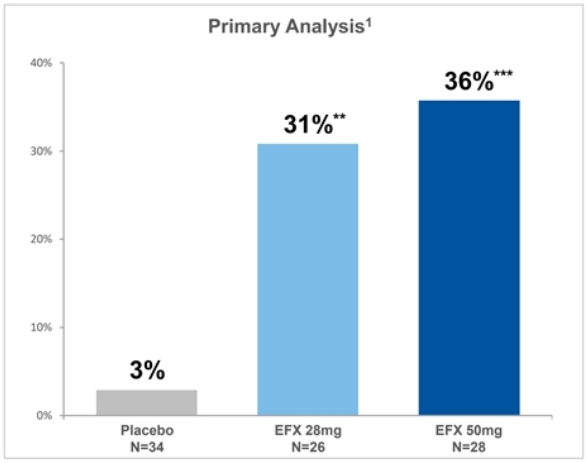
Fibrosis Improvement 2 Stages & No Worsening of MASH at Week 96



[1] All subjects with baseline and Week 96 biopsies ** p<0.01, *** p<0.001, versus placebo (CMH)

ITT Analysis[2]

Placebo (N=43)	EFX 28mg (N=40)	EFX 50mg (N=43)
2%	20%**	23%**

[2] Subjects with missing biopsies are imputed as non-responders

** p<0.01, versus placebo (CMH)

Source Data: LBAS-96; ITT

EFX Fibrosis Improvement in Context: Pre-Cirrhotic MASH:
≥2 Stage Improvement in Fibrosis & No Worsening of MASH

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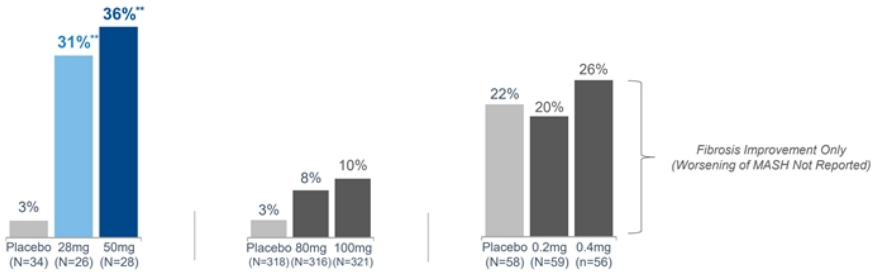
Efruxifermin
Phase 2b (F2-F3)
96 Wks / 66% F3
Consensus Readers
Completers[1]

Resmetirom
Phase 3 (F1-F3)
52 Wks / 62% F3
Two Readers
ITT[2]

Semaglutide
Phase 2b (F2-F3)
72 Wks / 69% F3
Consensus Readers
ITT[2]



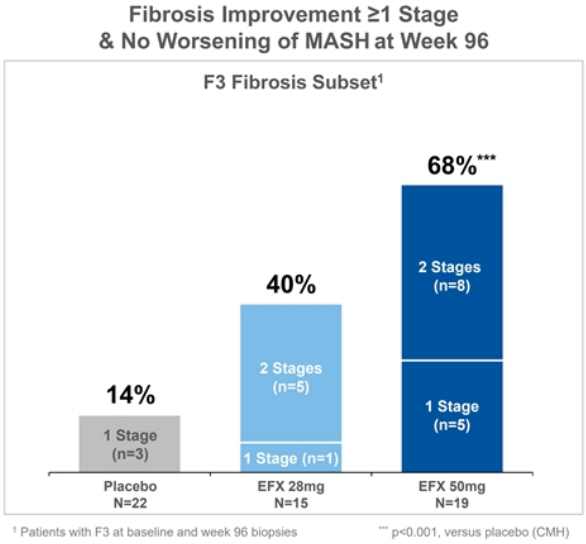
Note: These data are derived from different clinical trials at different points in time, with differences in trial design and patient populations. As a result, cross-trial comparisons cannot be made, and no head-to-head clinical trials have been conducted.

** p<0.01, versus placebo (CMH)

[1] Baseline and end-of-study biopsies available; [2] Missing biopsies imputed as non-responders

Pegozafermin - 89Bio (2023) March 22 Corporate Presentation; Denifanstat – Sagimet (2024) January 22 Press Release; Resmetirom – Madrigal (2022) December 19 Press Release; Semaglutide - Newsome et al. (2021) New Engl J Med 384, 1113-24

≥1 Stage Fibrosis Improvement & No Worsening of MASH:
Statistically Significant Response **Among F3 Patients** Observed for 50mg EFX



[1] Patients with F3 at baseline and week 96 biopsies

*** p<0.001, versus placebo (CMH)

Source Data: LBAS-96 (F3 Subgroup, N=56)

MASH Resolution & No Worsening of Fibrosis:
Statistically Significant Response Observed for Both EFX Groups

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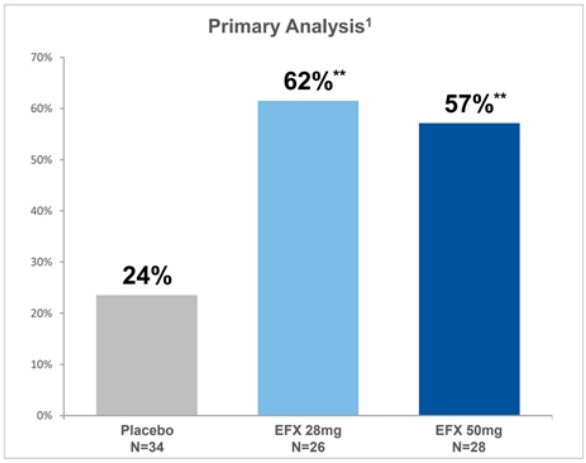
MASH Resolution
& No Worsening of Fibrosis at Week 96



[1] All subjects with baseline and Week 96 biopsies

** p<0.01, versus placebo (CMH test)

ITT Analysis[2]

Placebo (N=43)	EFX 28mg (N=40)	EFX 50mg (N=43)
19%	40%*	37%*

[2] Subjects with missing biopsies are imputed as non-responders

* p<0.05, versus placebo (CMH test)

Source Data: LBAS-96; ITT

≥1 Stage Fibrosis Improvement AND MASH Resolution:
Statistically Significant Response Observed for Both EFX Groups

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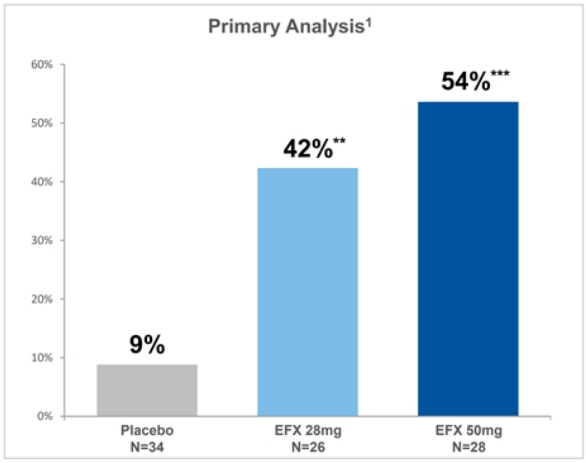
Fibrosis Improvement ≥1 Stage AND MASH Resolution at Week 96



[1] All subjects with baseline and Week 96 biopsies ** p<0.01, *** p<0.001, versus placebo (CMH)

ITT Analysis[2]

Placebo (N=43)	EFX 28mg (N=40)	EFX 50mg (N=43)
7%	28%**	35%**

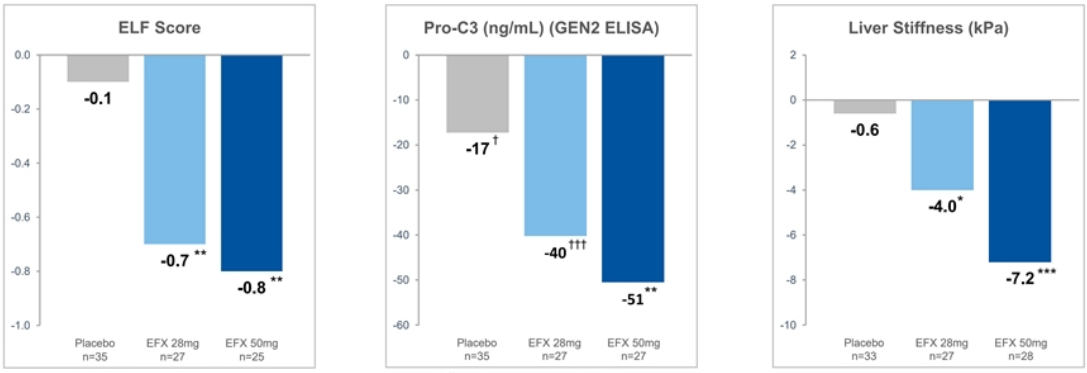
[2] Subjects with missing biopsies are imputed as non-responders

** p<0.01, versus placebo (CMH)

Source Data: LBAS-96; ITT

Statistically Significant Reductions in Non-Invasive Markers Reflect Histological Improvement in Fibrosis

LS Mean Change From Baseline to Week 96



** p<0.01, versus placebo
(Mixed Model Repeated Measures [MMRM])

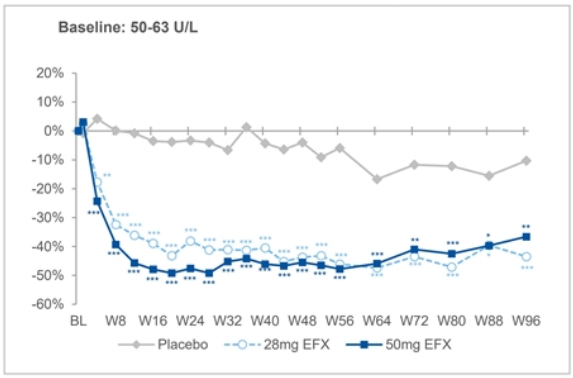
** p<0.01, versus placebo (MMRM)
† p<0.05, ††† p<0.001, versus baseline (MMRM)

* p<0.05, *** p<0.001, versus placebo
(MMRM)

Source Data: Biomarker Analysis Set (BMAS) (Pro-C3 and ELF); FAS (Liver Stiffness) (non-missing values only, no imputation)

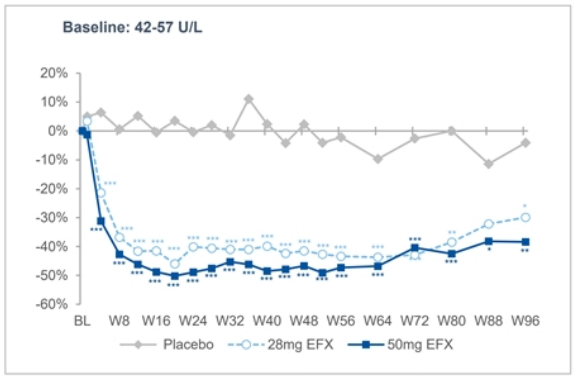
Statistically Significant Improvements in Markers of Liver Injury Sustained Through Week 96

ALT
LS Mean Percent Change from Baseline



* p<0.05,** p<0.01, *** p<0.001, versus placebo (MMRM)

AST
LS Mean Percent Change from Baseline



* p<0.05,** p<0.01, *** p<0.001, versus placebo (MMRM)

Source Data: FAS

Treatment-Emergent Adverse Events (TEAE)
From Baseline through Week 96

TEAE Overview	Placebo (N=43)	EFX 28mg (N=40)	EFX 50mg (N=43)
TEAE Leading to Death	0 (0%)	0 (0%)	0 (0%)
Drug-Related Serious Adverse Events (SAEs)	0 (0%)	1 (2%)[a]	1 (2%)[b]
Non-drug-related SAEs	4 (9%)[c]	3 (8%)[d]	6 (14%)[e,f]
Drug-Related TEAE Leading to Discontinuation	0 (0%)	4 (10%)[g,h]	3 (7%)[i,j]
Non-drug-related TEAE Leading to Discontinuation	0 (0%)	0 (0%)	2 (5%)[k,l]
Most Frequent (≥15%) Drug–Related TEAEs	**Placebo**	**EFX 28mg**	**EFX 50mg**
Diarrhea	7 (16%)	16 (40%)	16 (37%)
Nausea	5 (12%)	12 (30%)	14 (33%)
Increased Appetite	3 (7%)	7 (18%)	10 (23%)
Injection Site Erythema	6 (14%)	8 (20%)	7 (16%)
Injection Site Bruising	2 (5%)	6 (15%)	3 (7%)

[a] 28mg EFX, drug-related SAE (post week 24): pancreatitis (not confirmed on imaging and discharged within 24 hours)
[b] 50mg EFX, drug-related SAE (previously reported): esophagitis
[c] Placebo, non-drug-related SAEs (post week 24): (1) appendicitis; (2) osteoarthritis; (3) chest pain; non-cardiac; (4) hypoxia
[d] 28mg EFX, non-drug-related SAEs (post week 24): (1) gastritis; (2) ankle fracture; lower limb fracture (car accident); (3) coronary arteriospasm; panic attack
[e] 50mg EFX, non-drug-related SAEs (previously reported): (1) COVID-19 viral infection; (2) edema, face; (3) acute necrotizing pancreatitis
[f] 50mg EFX, non-drug-related SAEs (post week 24): (1) atypical chest pain (non-cardiac) radiation to the back; (2) acute chest pain; (3) acute respiratory failure
[g] 28mg EFX, drug-related AEs leading to discontinuation (previously reported): (1) increased appetite & weight gain; (2) diarrhea;
[h] 28mg EFX, drug-related AEs leading to discontinuation (post week 24): (1) pancreatitis (SAE reported above); (2) diarrhea
[i] 50mg EFX, drug-related AEs leading to discontinuation (previously reported): (1) esophagitis & vomiting; (2) nausea
[j] 50mg EFX, drug-related AE leading to discontinuation (post week 24): (1) diarrhea
[k] 50mg EFX, non-drug-related AE leading to discontinuation (previously reported): (1) lymphadenopathy
[l] 50mg EFX, non-drug-related AE leading to discontinuation (post week 24): (1) acute necrotizing pancreatitis

Source Data: Safety Set

» Safety Overview

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Blood Pressure

- No statistical difference versus placebo in systolic & diastolic BP at week 96

Markers of Liver Function and Hemostasis

- Remained stable, including platelets, bilirubin, INR[1], MELD[2] and CP[3] score

Progression to Cirrhosis

- Balanced across dose groups

Bone Mineral Density (BMD)

- Majority of patients in HARMONY were of post-menopausal age, among whom annual loss of BMD is generally expected to be 1 to 1.5%
- At week 48, no significant changes versus placebo for lumbar spine and femoral neck regions
- The placebo group experienced an approximately 1% increase in lumbar spine BMD by week 96
- At week 96, significant reductions versus placebo for lumbar spine (3-4%, both EFX groups) and femoral neck regions (< 3%, 50mg EFX only)
- One vertebral fracture (L1) observed in placebo group; no vertebral fractures observed in EFX groups

[1] Prothrombin International Normalized Ratio; [2] Model for End-Stage Liver Disease; [3] Child-Pugh

» Improvement in Lipoprotein Profile After 96 Weeks

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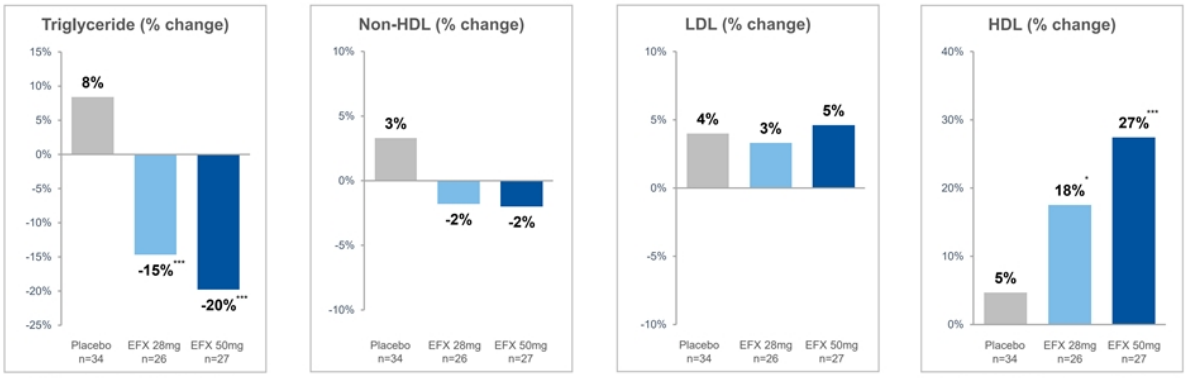
LS Mean Change From Baseline to Week 96 (%)



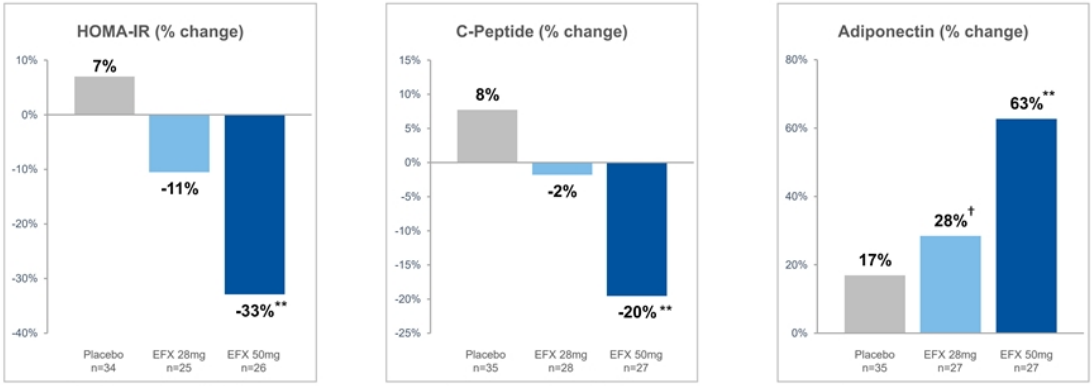
*** p<0.001, versus placebo (MMRM)

* p<0.05,*** p<0.001, versus placebo (MMRM)

Source Data: FAS, non-missing values only, no imputation

Insulin Sensitivity Remains Significantly Improved after 96 Weeks of Treatment with 50mg EFX

LS Mean Percentage Change From Baseline to Week 96



** p<0.01, versus placebo (MMRM)

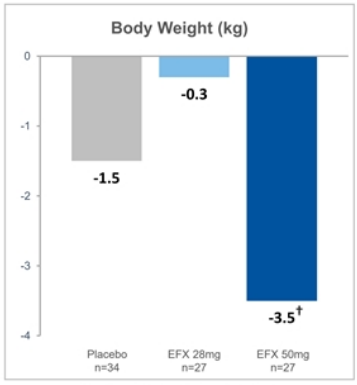
** p<0.01, versus placebo (MMRM)

** p<0.01, versus placebo (MMRM)
† p<0.05, versus baseline (MMRM)

Source Data: BMAS

Trend to Loss of Body Weight Maintained Over 96 Weeks of Treatment with 50mg EFX

LS Mean Change From Baseline to Week 96



† p<0.05, versus baseline (MMRM)

Source Data: FAS, non-missing values only, no imputation

» HARMONY Take-Aways: 50mg EFX After 96 Weeks

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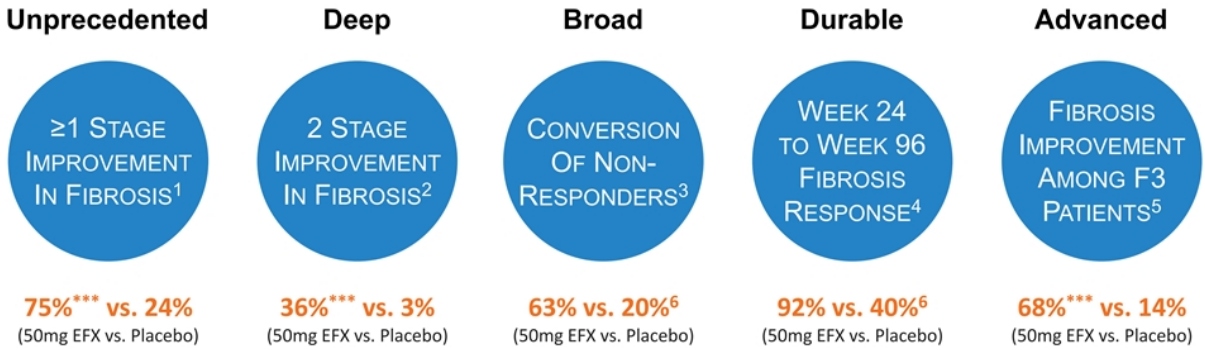

***** p<0.001, versus placebo (CMH)**

[1] ≥1 stage improvement in fibrosis without worsening of MASH; [2] 2 stages improvement in fibrosis without worsening of MASH; [3] proportion of Week 24 non-responders who converted to week 96 responders; [4] proportion of Week 24 responders who were also week 96 responders; [5] ≥1 stage improvement in fibrosis without worsening of MASH among patients with week 96 biopsies and F3 fibrosis at baseline; [6] Not evaluated for statistical significance

Source Data: LBAS-96

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